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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,763	04/13/2006	Shigehiko Mizutani	47234-5005-00-US (224018)	3821
55694 7590 07/18/2008 DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209				
EXAMINER				
GUSSOW, ANNE				
ART UNIT		PAPER NUMBER		
1643				
MAIL DATE		DELIVERY MODE		
07/18/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/575,763

**Applicant(s)**

MIZUTANI, SHIGEHICO

**Examiner**

ANNE M. GUSSOW

**Art Unit**

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-15 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 12, 14, and 15 have been amended.  
Claims 1-11 and 16 have been cancelled.
2. Claims 12-15 and 17 are under examination.
3. Upon further consideration by the examiner the finality of the previous office action has been withdrawn.
4. The following office action contains NEW GROUNDS of Rejection.

***Rejections Withdrawn***

5. The rejection of claims 11-15 under 35 U.S.C. 102(a) as being anticipated by Suzuki, et al. is withdrawn in view of applicant's cancellation of claim 11.

***NEW GROUNDS of Rejection***

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 1643

7. Claims 12-15 and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by Suzuki, et al. (Clinical Cancer Research, 2003. Vol. 9, pages 1528-1534, as cited in a previous office action).

The claims recite a method for prognostic evaluation of a P-LAP positive carcinoma in a patient, comprising: (a) contacting P-LAP positive carcinoma tissues obtained from said patient with an anti-P-LAP antibody, (b) measuring the intensity of the specific antigen-antibody binding between P-LAP present in the carcinoma tissues and anti-P-LAP antibody, and (c) correlating the intensity of the specific antigen antibody binding with a ten-year disease-free survival rate (DFS) of said patient, wherein the carcinoma is gynecological carcinoma, wherein the gynecological carcinoma is endometrial endometrioid adenocarcinoma, cervical carcinoma or ovarian carcinoma, wherein the anti-P-LAP antibody is an anti-human P-LAP antibody, wherein the anti-P-LAP antibody is an anti-human P-LAP polyclonal antibody.

Suzuki, et al. teach enhanced P-LAP expression in high-grade adenocarcinomas (figure 1, page 1530) detected by immunohistochemistry with an anti-human polyclonal P-LAP antibody (page 1529, 1st column). The active method steps of claim 17 are a and b. Step c is a mental step which is inferred by Suzuki, et al. that increased expression of P-LAP would be correlated with poorer survival rates since increased expression is associated with higher grade cancer. Since the claims do not define the specific P-LAP antibody and since Suzuki, et al. performed the active method steps a and b of claim 17, all the limitations of the claims have been met.

***Conclusion***

8. No claims are allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

July 15, 2008

/David J Blanchard/  
Primary Examiner, Art Unit 1643